DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 22 1998

Re: STROMECTOL®
Docket No. 97E-0061

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The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, D.C. 20231

ASSISTANT SECRETARY
AND COMMISSIONER
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U.S. PATENT
AND
TRADEMARK OFFICE

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,199,569, filed by Merck & Co., Inc., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for STROMECTOL®, the human drug product claimed by the patent.

The total length of the regulatory review period for STROMECTOL® is 2,291 days. Of this time, 2,055 days occurred during the testing phase and 236 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: August 17, 1990.

   The applicant claims July 17, 1990, as the date the Investigational New Drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 17, 1990, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: April 1, 1996.

   The applicant claims March 29, 1996, as the date the New Drug Application (NDA) for STROMECTOL® (NDA 50-742) was initially submitted. However, FDA records indicate that NDA 50-742 was submitted on April 1, 1996.

3. The date the application was approved: November 22, 1996.

   FDA has verified the applicant's claim that NDA 50-742 was approved on November 22, 1996.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Thomas J. McGinnis

Thomas J. McGinnis, R.Ph.
Deputy Associate Commissioner
for Health Affairs

cc: David L. Rose
Merck & Co., Inc.
P.O. Box 2000
Rahway, NJ 07065-0907